

OCT 17 2005

510(k) SUMMARY

Rotator Cuff Quickanchor Plus

Submitter's Name and Address:

DePuy Mitek
a Johnson & Johnson company
249 Vanderbilt Avenue
Norwood, MA 02062

Contact Person

Denise Luciano
Senior Regulatory Affairs Specialist
DePuy Mitek
a Johnson & Johnson company
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Norwood, MA 02062
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Name of Medical Device

Classification Name: Screw, Fixation, Bone Staple
Common/Usual Name: Smooth or threaded metallic bone fixation fastener
Proprietary Name: Rotator Cuff Quickanchor Plus

Substantial Equivalence

Rotator Cuff Quickanchor Plus (with ORTHOCORD) is substantially equivalent to:
Rotator Cuff Quickanchor Plus, K992611, manufactured by DePuy Mitek.

Device Classification

Bone anchors/screws are classified by the FDA as Class II Medical Devices under the generic category of Smooth or threaded metallic bone fixation fasteners.

Rotator Cuff Quickanchor Plus carry FDA product code HWC, and is classified as a fixation fastener under 21 CFR 888.3040.

Device Description

Rotator Cuff Quickanchor Plus (with ORTHOCORD) is a preloaded, metallic disposable suture anchor/ inserter assembly designed to allow soft tissue repair to bone. The metal anchor is an identical anchor as that of the Rotator Cuff Quickanchor Plus in design, configuration and

510(k) Premarket Notification: Special
Rotator Cuff Quickanchor Plus

Confidential

dimensions. The anchor system may be sold with Ethibond Suture (NDA 17-804 and 17-809), Panacryl Suture (K964345), or Orthocord Suture (K040004 and K043298).

Indications for Use

The Mitek Rotator Cuff QuickAnchor[®] Plus is indicated for Rotator cuff repair.

Safety and Performance

The determination of substantial equivalence for this device was based on a detailed device description, and conformance to consensus and voluntary standards. Bench testing was performed demonstrating that the ORTHOCORD suture conformed to the USP monograph for absorbable sutures, and the suture compatibility and deployment met predetermined acceptance criteria.

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Rotator Cuff QuickAnchor Plus has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 17 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Denise Luciano
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DePuy Mitek
a Johnson & Johnson Company
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Norwood, Massachusetts 02062

Re: K052630
Trade/Device Name: Rotator Cuff Quickanchor Plus
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: September 23, 2005
Received: September 26, 2005

Dear Ms. Luciano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K052630

Device Names: Rotator Cuff Quickanchor Plus

Indications for Use:

The Mitek Rotator Cuff QuickAnchor® Plus is indicated for Rotator cuff repair.


Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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